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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,212	12/11/2003	Donald W. Kufe	00530-095002 / 718.09	7998

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FISH & RICHARDSON P.C.
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER

HILL, KEVIN KAI

ART UNIT PAPER NUMBER

1633

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/733,212	Applicant(s) KUFE, DONALD W.	
	Examiner Kevin K. Hill, Ph.D.	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) 2-4 and 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5 and 7-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>Feb. 25, 2005</u> | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

1. Applicant's response to the Requirement for Restriction, filed on August 17, 2006 is acknowledged.

Applicant has elected the invention of Group I, claims 1-8, drawn to a method of identifying a compound that inhibits binding of MUC1 to a tumor progressor. Furthermore Applicant elects the species (iv) β -catenin (Claim 5). The election is made without traverse.

Because applicant did not distinctly and specifically point out the supposed errors in the Group or species restriction requirement, the restriction and election requirement is deemed proper and therefore made final (MPEP § 818).

2. Claims 2-4 and 6 are pending but withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention, there being no allowable generic or linking claim.

3. Claims 1, 5 and 7-8 are under consideration.

Priority

4. Applicant's claim for priority under 35 U.S.C. 119(e) or 120 regarding the parent provisional application 60/257,590, filed on December 22, 2000 and provisional application 60/308,307, filed on July 27, 2001 is acknowledged. It is noted that the amendment to the specification filed on December 11, 2003 states: "This application claims priority of U.S. Application No. 10/032,786, filed December 26, 2003 [emphasis added]." According to the Office records, Application No. 10/032,786 was filed December 26, 2001.

The effective priority date of the instant application is granted as December 22, 2000.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5 and 7-8 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: The method does not provide a correlation between identifying a compound that inhibits binding of the MUC1 *test agent* [emphasis added] to the tumor progressor *test agent* [emphasis added] with identifying a compound that inhibits binding of MUC1 with a tumor progressor. The last step of the method, step (d), does not iterate the preamble. Claims 5 and 7-8 are rejected, as being dependent on Claim 1.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 1, 5 and 7 are rejected under 35 U.S.C. 102(b)** as being anticipated by Yamamoto et al (J. Biol. Chem. 272(19): 12492-12494, 1997).

The claims are drawn to a method of identifying a compound that inhibits binding of MUC1 to a tumor progressor, wherein the tumor progressor test agent is beta-catenin (β ctn), and wherein the contacting step occurs in a cell-free system. Applicant contemplates that the method may be performed using isolated MUC1 and tumor progressor test agents (pg 20, line 6, 20-24). The tumor progressor test agent can be immobilized on a solid substrate such as a nylon or nitrocellulose membrane and then exposed to the MUC1 test agent in the presence and absence of the test compound (pg 21, lines 19-24).

Yamamoto et al teach that the MUC1 cytoplasmic domain recognizes both β ctn and gamma-catenin (γ ctn) when tested by immunoprecipitation from cell lysates and in a filter-binding assay, wherein the catenin test agents are bound to a nitrocellulose membrane and

incubated in the presence of a GST-MUC1/CD test agent (pg 12493; Figures 1-2). Yamamoto et al also teach that incubation of the MUC1 test agent with the peptide GGSSLSY inhibited the binding of MUC1 to β ctn and γ ctn in the context of the immunoprecipitation and filter-binding assays (pg 12493; Figure 3).

Thus, Yamamoto et al anticipate Claims 1, 5 and 7.

6. **Claims 1, 5 and 8 are rejected under 35 U.S.C. 102(b)** as being anticipated by Li et al (Mol. Cell Biol. 18(12): 7216-7224, 1998, * of record in IDS).

The claims are drawn to a method of identifying a compound that inhibits binding of MUC1 to a tumor progressor, wherein the tumor progressor test agent is beta-catenin (β ctn), and wherein the contacting step occurs in a cell. The specification does not define the structural metes and bounds of the inhibitory test compound; however, Applicant contemplates that the compound to be identified by the method includes those compounds that inhibit the binding between MUC1 and a tumor progressor, e.g. the instantly preferred embodiment being β ctn (pg 27, lines 7-10).

Li et al teach that 293 and HeLa cells transfected with plasmids expressing kinase-active GSK-3 β , resulting in significantly decreased interactions between MUC1 and β ctn (pg 7219; see also pg 7220, Figure 5).

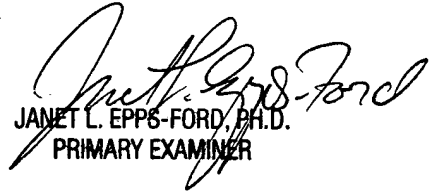
Thus, Li et al anticipate Claims 1, 5 and 8.

7. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin K. Hill, Ph.D. whose telephone number is 571-272-8036. The examiner can normally be reached on Monday through Friday, between 9:00am-6:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


JANET L. EPPS-FORD, PH.D.
PRIMARY EXAMINER